OCT 2 2 2004

510(k) SUMMARY
Cardiva Medical, Inc.
VasoStasis™ Vascular Closure System
510(k) Notification K041486

GENERAL INFORMATION

Manufacturer: Cardiva Medical, Inc.
2585 Leghorn Street
Mountain View, CA 94043
Phone: (650) 964-8900
Facsimile: (650) 964-8911
Establishment Registration Number: 3004182619

Contact Person: Augustine Lien
Founder, Chairman and CEO

Date Prepared: October 15, 2004

DEVICE INFORMATION

Trade name: VasoStasis™ Vascular Closure System

Classification Names: Vascular Clamp (21 C.F.R. § 870.4450);
Catheter, Intravascular, Diagnostic (21 C.F.R. § 870.1200);
Surgical Vessel Dilator (21 C.F.R. § 870.4475);
Blood Access Device and Accessories (21 C.F.R. § 870.5540)

Classification: Class II

PREDICATE DEVICES

1. Radi Medical Systems AB, FemoStop™ System
2. Instromedix, Inc., COMPRESSAR® Universal System
3. CardioThoracic Systems, Inc., CTS FloCoil™ Shunt
4. Bio-Vascular, Inc., Flo-Rester® Internal Vessel Occluder

INTENDED USE/INDICATIONS FOR USE

The Cardiva Medical VasoStasis Vascular Closure System is intended to promote hemostasis at arteriotomy sites as an adjunct to manual compression. The VasoStasis Vascular Closure System is indicated for use in patients undergoing diagnostic femoral artery catheterization procedures, using 5 or 6 Fr introducer sheaths.

DEVICE DESCRIPTION

The VasoStasis Vascular Closure System consists of the following components: (1) a sterile. disposable catheter (VasoStasis™ VCS Catheter), and (2) a sterile, disposable tensioning device (VasoStasis™ VCS Tensioner). The VasoStasis Vascular Closure System, in conjunction with manual compression, provides hemostasis at femoral access sites after femoral arterial catheterization while allowing continued perfusion of the lower extremities.

The VasoStasis VCS Catheter is a single lumen, low profile catheter with an elastomeric membrane at the distal tip. The membrane is covered by a tip guide, which protects the membrane as the de-deployed catheter is inserted into the artery through a previously placed introducer sheath. A small loop handle is at the proximal end of the device and moves axially to deploy or de-deploy a Nitinol coil within the membrane. Once the catheter is introduced into the vessel, the membrane is positioned distal to the introducer sheath and deployed by pushing the loop handle forward. In its fully deployed state, the membrane nominally achieves 13 F in diameter. The Cardiva VasoStasis VCS Tensioner clips on the VasoStasis VCS Catheter shaft on the surface of the skin at the entrance to the arteriotomy and holds the catheter secure while the membrane is deployed in the vessel.

METHOD OF USE

The VasoStasis VCS Catheter is inserted through a previously placed catheter introducer sheath in its de-deployed state. Once positioned, the VasoStasis VCS Catheter membrane is deployed in the inner lumen of the femoral artery and is physically seated against the arterial wall at the arteriotomy site by the user. The VasoStasis VCS Tensioner is applied to the shaft of the VasoStasis VCS Catheter on the surface of the skin at the entrance to the arteriotomy to control movement of the membrane and to provide a slight upward tension on the system to ensure that the membrane remains seated against the arteriotomy and hemostasis is maintained. This membrane provides temporary occlusion of the arteriotomy while the natural mechanisms of hemostasis are enacted. Closure of the arteriotomy occurs when the smooth muscle wall of the artery and the fascial tract contract, and the blood remaining in the tract coagulates. The VasoStasis VCS does not have any mechanism to alter or manipulate the natural response of the body, and no part of the device remains in the patient after it is removed.

DATA DEMONSTRATING SUBSTANTIAL EQUIVALENCE

Bench performance testing of the VasoStasis Vascular Closure System demonstrated that the System meets or exceeds the performance requirements for the intended clinical use of the device. The results demonstrated that the VasoStasis Vascular Closure System satisfies all of its performance requirements, which are designed to ensure that the System is safe and effective for its intended use.

Biocompatibility testing of all device components and materials was conducted pursuant to FDA's Guidance Document (#G95-1), Use of International Standard ISO-10993-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing (1995), which specifically outlines the types of biocompatibility tests that are required based on the nature of the device and the extent and duration of its contact with blood or tissues. Additional tests have also been conducted according to ISO 10993-4, "Biological Evaluation of Medical Devices, Part 4, Selection of Tests for Interaction with Blood." Based on the test results the VasoStasis Vascular Closure System has been demonstrated to be biocompatible.

The performance and safety of the VasoStasis Vascular Closure System were evaluated *in vivo* in several animal models. A number of animal studies have been conducted: acute animal studies, a chronic animal study, as well as device performance verification studies. The acute animal study evaluations support the safe and effective use of this type of system to control bleeding and promote hemostasis at the arteriotomy site following femoral artery catheterization procedures. The chronic animal study was conducted to evaluate the ability to place the device in the femoral artery through an arterial access introducer sheath, deploy the device, place it in tension and achieve hemostasis. Three animals were then survived for a period of three weeks after which tissue harvests were obtained to observe for any adverse tissue responses and evaluated for natural healing responses after treatment. Several animal studies were also conducted to evaluate certain performance characteristics of the VCS, including positioning techniques and membrane pull-through force. The animal studies conducted support the performance and safety of the VasoStasis Vascular Closure System.

Four Cardiva Medical and BioInterventional (former Company) sponsored clinical studies were conducted with the VasoStasis VCS and prior versions of the technology comprising an evaluation of a total of 441 patients (one enrolled but not treated). The four separate clinical studies evaluated the safety and effectiveness of the system. Initial clinical evaluations, sponsored by BioInterventional were conducted in Germany and in Canada. These studies were followed by two Non-Significant Risk Clinical Evaluations in the United States, one sponsored by BioInterventional (US I) and one sponsored by Cardiva Medical (US II).

Summaries of the clinical evaluations were provided and the results support the safe and effective use of the current VasoStasis VCS for its intended use. The German clinical evaluation was a post-market European study evaluating a total of 144 patients. The US II, US I, and Canadian Clinical Studies comprised an evaluation of a total of 278 consecutive phase patients. The data obtained from the prospective Canadian Clinical Study was retrospectively analyzed using the same outcome definitions as the US II and US I Studies. The clinical results obtained from the US II, US I and Canadian clinical evaluations demonstrate the safety and effectiveness of the VasoStasis Vascular Closure System as an adjunct to manual compression for providing hemostasis at arteriotomy sites in patients undergoing diagnostic femoral artery catheterization procedures. This was demonstrated by the observed device success rates (>70%) and low major complication rates (<5%). The average direct manual compression time and the average time to ambulation using the VasoStasis VCS were significantly less as compared to the literature control. The overall time to hemostasis, defined as the tension time plus direct manual compression time, was not decreased. Thus, the VasoStasis Vascular Closure System as an adjunct to manual compression is safe and effective in managing vascular access sites in patients who have had a percutaneous access procedure with a 5 or 6 French introducer sheath.

CONCLUSION

Performance, Biocompatibility, Animal Testing and Clinical Studies conducted demonstrate that the Cardiva Medical VasoStasis Vascular Closure System is safe and effective for its intended use and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 2 2004

Cardiva Medical, Inc.
c/o Mr. Augustine Lien
Chairman and CEO
2585 Leghorn Street
Mountain View, CA 94043

Re: K041486
Cardiva Medical VasoStasis™ Vascular Closure System
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II (two)
Product Code: DXC
Dated: October 6, 2004
Received: October 7, 2004

Dear Mr. Lien:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Vechinski

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K041486

Indications for Use

510(k) Number (if known): K041486

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Prescription Use _X_ (Part 21 CFR 801 Subpart D) OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vo Mussel

(Division Sign-Off)
Division of Cardiovascular Devices

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